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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,378	02/23/2004	George Goicoechea	BSI-210US9	8809

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EXAMINER	
BUI, VY Q	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,378	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	Vy Q. Bui	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-65* is/are pending in the application.

4a) Of the above claim(s) *63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-62,64 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/8/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

As indicated by the Applicant (paper 3/27/2008), claims 63 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant traversed the restriction because claim ! was stated as generic. However, claim 1 has been canceled. Claim 54 is generic.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54-62, 64-65 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fogerty-EP0686379A2.

As to claim 54, Fogerty-'379 (Fig. 5-12, for example) discloses a prosthesis assembly comprising a proximal prosthesis 20 having a proximal end and a distal end, the proximal prosthesis further having a proximal orifice at the proximal end to be located in and when expanded to be supported by a vascular vessel; at least one distal prosthesis 10; the proximal prosthesis also having at least one distal orifice at the distal end which when expanded serves to receive a proximal end of the at least one distal prosthesis 10, wherein the proximal prosthesis 20 and the at least one distal prosthesis 10 each comprises an expandable stent 14 of shape memory alloy nitinol (col. 8, line 56 to col. 9, line 75) and at least one fabric layer 12 (col. 10, ll. 13-24) over and/or in the expandable stent 14; and wherein a cross-sectional area of

the distal orifice when expanded is sufficiently less than that of the proximal end of the at least one distal prosthesis when expanded within the distal orifice so as to form a seal between the proximal and distal prostheses. Figs. 8-11 show distal prosthesis 10 placed inside proximal prosthesis 20 to prevent a blood flow leaking from assembly of distal prosthesis 10 and distal prosthesis 20 into aneurysm location. Inherently, inside distal prosthesis 10 must be bigger than outside proximal prosthesis 20 to have a seal and tight fit between inside distal prosthesis 10 and outside proximal prosthesis 20. Alternatively, it would have been obvious to one of ordinary skill in the art to provide a tight and seal fit between inside distal prosthesis 10 and outside proximal prosthesis 20 so that no blood will leak out from the tight fit between inside distal prosthesis 10 and outside proximal prosthesis 20.

As to claim 55, the distal end of the proximal prosthesis 20 has a first intermediate portion which is extended to form a distal portion, and a second intermediate portion which has a distal orifice which has a relatively short inclined extension (see Fig. 8-12) to enable the distal prosthesis 10 to be located therein when the short extension has been expanded, the distal prosthesis having a proximal end which when expanded will form a seal with the short extension.

As to claim 56, wherein the distal end of the proximal prosthesis 20 has first and second distal portions, the first distal portion having the at least one distal orifice and the second distal portion having another distal orifice for the receipt of the at least one distal prosthesis 10, each of which will have a stent 14 expandable to a cross-sectional area sufficiently greater than the cross-sectional area(s) of the distal orifices so that effective seals are formed.

As to claims 57-59, Fogerty-'379 (Fig. 5-12, for example) discloses prosthesis assembly comprising a) a proximal prosthesis 20 having a distal end, the proximal prosthesis 20 being

expandable and having a proximal orifice; b) first and second distal prostheses 10; c) the proximal prosthesis 20 also having a distal orifice at the distal end that when expanded receives at least one proximal end of the first and second distal prostheses; d) wherein each of the proximal 20 and distal prostheses 10 comprises an expandable stent 14 of shape memory alloy nitinol (col. 8, line 56 to col. 9, line 75) and at least one fabric layer 12 (col. 10, ll. 13-24) over and/or in the stent 14; and e) wherein a cross-sectional area of the distal orifice of the proximal prosthesis when expanded is sufficiently less than the sum of cross-sectional areas of the proximal ends of the distal prostheses when expanded within the distal orifice, so as to form a seal with the distal orifice when the distal prostheses are expanded therein and distal prosthesis 10 each comprises an expandable stent 14 of shape memory alloy nitinol (col. 8, line 56 to col. 9, line 75).

As to claim 60, Fogerty-'379 (Fig. 5-12, for example) discloses a prosthesis assembly comprising a proximal prosthesis 20, a pair of distal prostheses 10, the proximal prosthesis 20 being expandable and having a distal end and a proximal orifice, the proximal prosthesis 20 also having a distal orifice at the distal end which when expanded serves to receive proximal ends of the pair of distal prostheses 10, wherein each of the proximal and distal prostheses 20 and 10 comprises an expandable stent 14 of shape memory alloy nitinol (col. 8, line 56 to col. 9, line 75) and at least one fabric layer 12 (col. 10, ll. 13-24) over and/or in the stent, and wherein the cross-sectional area of the distal orifice of the proximal prosthesis 20 when expanded is sufficiently less than the sum of the cross-sectional areas of the proximal ends of the distal prostheses 20 when expanded within the distal orifice so as to form a seal with the distal orifice when the pair of distal prostheses 10 are expanded therein.

As to claim 61, wherein a portion of at least one of said proximal prosthesis 20 and said distal prosthesis 10 has a different radiopacity because they are structurally different, said

portion of different radiopacity facilitating proper alignment of said proximal and distal prostheses.

As to claim 64, the Fogerty-'379's prosthesis assembly (Fig. 12) being configured for placement at an angeological bifurcation of a vessel into two branched vessels, said proximal prosthesis.defining two lumens, at least one of which is configured to be disposed entirely within said vessel and is adapted to mate with said distal prosthesis configured to extend into one of the two branched vessels.

As to claim 65, the Fogerty-'379 prosthesis assembly comprising a male engaging portion on said distal prosthesis 10, and a female portion on said proximal prosthesis 20, said male engaging portion being configured to be positioned at least partially within said female portion for inter-engagement between the outer surface of said male engaging portion and the inner surface of said female portion to resist longitudinal movement to prevent separation of said male engaging portion from said female portion, each of said male engaging portion and said female portion comprising a stent 14 and at least one of said proximal prosthesis 20 and said distal prosthesis 10 comprising a fabric layer 12 attached to said stent 14, said fabric layer 12 being configured to be interposed between said male engaging portion and said female portion to form a substantially fluid-tight seal upon assembly.

Response to Arguments

Claim 54-60 have been asserted by the Applicant as copied claims from U.S. Pat. No. 6,524,336 (Papazolgou et al.). However, there are differences between the claims languages of claims 54-60 and Papazolgou-'336's claims. Therefore, claims 54-60 are not considered as

copied claims and a Technology Center Director's approval of the rejection is not required. In addition, this case is not an interference case until claims 54-60 are allowed.

As informed by the Applicant (page 5 of 6, paper 1/28/2009), priority of Fogarty (Medtronic's) has been awarded by the Board in its July 27, 2001 final decision and judgment. Therefore, Fogarty is proper prior art reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fogerty-EP0686379A2 over Piplani et al.-5,489,295.

Fogerty-EP0686379A2 does not explicitly disclose radiographic indicia on the prosthesis. However, it is well known to have radiographic indicia on a prosthesis for locating the location of the prosthesis. For example, Piplani et al.-5,489,295's Fig. 4, shows radiographic indicia 121 for monitoring the location of the prosthesis 20 inside a patient's body. It would have been obvious to one of ordinary skill in the art to provide radiographic indicia as taught by Piplani-'295 to a Fogerty-EP0686379A2 prosthesis so that one can monitor the location of the prosthesis inside a patient's body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/
Primary Examiner, Art Unit